



**UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/063,978	04/21/98	OBREMSKI	R 45D-1750 (641

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HM22/0110

EXAMINER

HINES, J

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

01/10/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Advisory Action

Application No.  
09/063,978

Applicant(s)  
Obremski et al.

Examiner  
Ja-Na Hines

Group Art Unit  
1645



THE PERIOD FOR RESPONSE: [check only a) or b)]

- a) ☐ expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on \_\_\_\_\_ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on Dec 5, 2000 has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:

☒ The proposed amendment(s):

☒ will be entered upon filing of a Notice of Appeal and an Appeal Brief.

☐ will not be entered because:

- ☐ they raise new issues that would require further consideration and/or search. (See note below).
- ☐ they raise the issue of new matter. (See note below).
- ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
- ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

- ☐ Applicant's response has overcome the following rejection(s): \_\_\_\_\_

- ☐ Newly proposed or amended claims \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

- ☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:

The rejections of the previous office action are maintained. See attached advisory action.

- ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

- ☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: None

Claims objected to: None

Claims rejected: 1-26

- ☐ The proposed drawing correction filed on \_\_\_\_\_ ☐ has ☐ has not been approved by the Examiner.
- ☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Other

Art Unit: 1641

### **ADVISORY ACTION**

1. Claims 1-26 are pending in the Office Action.

### ***Response to Arguments***

2. Applicant's request for reconsideration filed December 5, 2000 have been fully considered but they are not persuasive.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4, 13-19, 21 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekins et al., (EP 304,202) in view of Ekins et al., (J. of Clinical Immuno.) Is maintained. Applicants argue that substantial depletion of the analyte is not taught by the combination of references. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, Ekins et al., (J. of Clinical Immuno.) teaches analyte binding by antibody clearly causes

Art Unit: 1641

analyte depletion in the surrounding medium. Accordingly, it would have been obvious at the time of applicants invention to use the technique of allowing for analyte depletion in a sample as taught by Ekins et al., (J. of Clinical Immun.) in the binding assay of Ekins et al., (EP 304,202) because this technique is already well known in the art for determining analyte concentration.

4. Claims 1-4, 13-19, 21 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekins et al., (EP 304,202) in view of Ekins et al., (Analytica Chimica Acta.) Is maintained. Applicants argue that the references do not teach substantial depletion of the analyte. However, Ekins et al., (Analytica Chimica Acta.) clearly teaches the analyte binding by antibody clearly causes analyte depletion in the surrounding medium. Further, no more than routine skill is required to implement well known techniques such as analyte depletion into the binding assay of Ekins et al. (EP 304,202). Therefore it would have been obvious at the time of applicants invention to use the technique of allowing for analyte depletion in a sample as taught by Ekins et al., (Analytica Chimica Acta.) in the binding assay of Ekins et al., (EP 304,202) because this technique is already well known in the art for determining analyte concentration.

5. Claims 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekins et al., (EP 304,202) and either Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica Chimica Acta.), in further view of Ullman et al., (US Patent 5,512,659) is maintained. Applicant's argue that there is no suggestion to combine the references because Ekins et al., (EP 304,202), or either

Art Unit: 1641

Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica Chimica Acta.), teach substantial depletion of the analyte. However, Ekins et al., (EP 304,202) and either Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica Chimica Acta.), have been discussed above.

Therefore, it would have been obvious at the time of applicants invention to have used the first binding partner, conjugate, biotin-avidin labels and biotinylated antibodies as taught by Ullman et al., in the method of Ekins et al., (EP 304,202) in view of either Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica Chimica Acta.) because Ullman et al., teaches that these methods are more versatile and convenient than the known methods.

6. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ekins et al., (EP 304,202), in view of either Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica Chimica Acta.) in further view of Waggoner et al., US Patent (5,368,486) is maintained.

Applicant argues that there is no suggestion to combine the references, because they do not teach substantial depletion. The Ekins et al., references have been discussed previously. No more than routine skill would have been required to use cyanine dyes as taught by Waggoner et al., in the method of Ekins et al., (EP 304,202) in view of either Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica Chimica Acta.) because Waggoner et al., teaches that these cyanine dyes are intrinsically more fluorescent; have improved photostability; improved water solubility; can label a wide variety of biological materials; and subject to a variety of excitation wavelengths using lasers.

Art Unit: 1641

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ekins et al., (EP 304,202) in view of either Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica Chimica Acta.) in view of Waggoner et al., US Patent (5,368,486) in further view of Lee et al., (US Patent 5,453,505) is maintained. Ekins et al., (EP 304,202), Ekins et al., (J. of Clinical Immuno.), Ekins et al., (Analytica Chimica Acta.) and Waggoner et al., have all been discussed previously however, none teaches the use of Cy5 or Cy7. In this case, it would have been obvious at the time of applicants invention to have used Cy5 or Cy7 as taught by Lee et al., in the method of Ekins et al., (EP 304,202) in view of either Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica Chimica Acta.), and Waggoner et al., US Patent (5,368,486), because Lee et al., teaches a reduced tendency to aggregate and enhanced photostability.

8. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ekins et al., (EP 304,202) in view of either Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica Chimica Acta.) in view of Northrup et al (US Patent 5,639,423) is maintained. Ekins et al., (EP 304,202) in view of either Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica Chimica Acta.) have been discussed previously. In this case, it would have been obvious at the time of applicants invention to use the well known method of dispensing material using a jet printer as taught by Northup et al., in the method of Ekins et al., (EP 304,202) in view of either Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica Chimica Acta.) because Northup et al., teaches that the method is especially advantageous for biochemical reactions.

Art Unit: 1641

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines *JNH*

December 18, 2000

*J Graser 12/19/00*  
**JENNIFER GRASER**  
**PATENT EXAMINER**